UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Hon. Patti Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories Inc., CIVIL ACTION NO. 06-11337-PBS	)	Magistrate Judge Marianne B. Bowler

THE UNITED STATES' OPPOSITION TO ABBOTT LABORATORIES INC.'S MOTION FOR A PROTECTIVE ORDER RELATING TO THE DEPOSITION OF DUANE BURNHAM AND THOMAS HODGSON

EXHIBIT 2

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

UNITED STATES OF AMERICA ex rel. VEN-A-CARE OF THE FLORIDA KEYS, INC., a Florida corporation, by and through its principal officers and directors, ZACHARY T. BENTLEY and T. MARK JONES, Plaintiff, v. ABBOTT LABORATORIES, INC. and HOSPIRA, INC., Defendants.	Case No.: 06-CV-21303-ASG Hon. Alan S. Gold

ABBOTT LABORATORIES, INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS

James R. Daly, Esq.
Admitted *pro hac vice*
Daniel E. Reidy, Esq.
Admitted *pro hac vice*
JONES DAY
77 West Wacker
Chicago, IL 60601-1692
Telephone: (312) 782-3939
Facsimile: (312) 782-8585
jrdaly@jonesday.com
dereidy@jonesday.com

Mark P. Schnapp, Esq.
Florida Bar No. 501689
Sabrina R. Ferris, Esq.
Florida Bar No. 419273
GREENBERG TRAURIG, P.A.
1221 Brickell Avenue
Miami, Florida 33131
Telephone: (305) 579-0541
Facsimile: (305) 579-0717
schnappm@gtlaw.com
ferriss@gtlaw.com

Counsel for Defendants
Abbott Laboratories, Inc. and Hospira, Inc.

The Medicare Carriers, who are responsible for determining the reimbursement amount, calculated this amount using an agency-promulgated methodology that took the median AWP for all sources of the product. For Medicaid, the Federal and State Governments used several reimbursement approaches; many were not even based on AWP.

B. Although The Government Has Known For Over 30 Years That AWP Is Not An Acquisition Cost, It Nonetheless Embraced AWP As A Reimbursement Methodology To Further Its Own Policy Objectives.

Many of the Program reimbursement methodologies set forth above rely on published "AWPs" for the products at issue. AWP is a term of art in the pharmaceutical industry. The AWP for pharmaceutical products is separately calculated and published by independent third-party compendia after they obtain the product's list price or Wholesale Acquisition Cost and apply their own formula to it. (Compl. ¶ 60.) The AWP is considered a "sticker price" by those who make, market, and buy pharmaceutical products, as well as by the Government. (*See, e.g.*, App. A, Tab 19 (1997 Presidential Radio Address by President Clinton: "[O]verpayments [for drugs] occur because Medicare reimburses doctors according to the published [AWP] – the so-called sticker price – for the drugs."); *id.*, Tab 16 (At a 1997 Senate Hearing HHS Secretary Donna Shalala states that "AWP is not the average price actually charged by wholesalers to their customers. Rather, it is a 'sticker' price . . . published in several commercial catalogs.").)

In fact, the Government has known for nearly 40 years that the compendia's published prices exceed by a substantial margin the product's actual acquisition cost. (*See* Appendix A, which provides and summarizes four decades worth of public documents showing the Government knew compendia prices were not acquisition costs.).[3] Indeed, as far back as

[3] This Court may, of course, take judicial notice of these public records on a Rule 12(b)(6) motion. *See Williams v. Edelman*, 408 F.Supp.2d 1261, 1264 (S.D. Fla. 2005); *In re Vertex Pharm., Inc., Sec. Litig.*, 357 F.Supp.2d 343, 352 n.4 (D. Mass. 2005); *see generally* Fed. R. Evid. 201(b), (d).

December 1968, the Federal Government's Task Force on Prescription Drugs[4] reported that compendia prices "do not reflect the actual manufacturers' prices to wholesalers and retailers . . . ." (App. A, Tab 1.)

Throughout the ensuing decades, both the Executive and Legislative Branches of the Government repeatedly acknowledged this fact. For example:

- In 1974 (32 years ago), when HEW was considering a Medicare reimbursement model that would have reimbursed providers for both the cost of a drug and a dispensing fee, it rejected using AWP for the "drug cost" portion because AWPs "are frequently in excess of actual acquisition cost to the retail pharmacist." (App. A, Tab 3.)

- In 1975 (31 years ago), HEW reported that "Average wholesale prices are frequently inflated and large purchasers can take advantage of buying in bulk, deriving greater profit." (App. A, Tab 6.)

- In 1984 (22 years ago), HCFA advised State Medicaid agencies that "AWP cannot be the best – or even an adequate – estimate of the price providers generally pay for drugs." (App. A, Tab 7.)

- In 1989 (17 years ago), a Congressional Staff Report confirmed that the Government itself, through the Veterans' Administration, "achieves an average discount of . . . 67% off the published AWP for multiple source drugs . . ., and hospitals, [HMOs] and nursing homes that contract with wholesalers . . . achieve discounts of up to 99% off [AWP]" – in other words, *there was a "spread" of nearly 10,000%* between the AWP and the actual wholesale price. (App. A, Tab 8.)

- In 1997 (9 years ago, 2 years after this suit was filed, and in the heart of the period for which Plaintiffs seek damages), the Office of the Inspector General ("OIG") for HHS reported, with respect to Vancomycin HCL – *one of the four pharmaceutical products at issue in this case* – that the Medicare allowed amount was $10.07, while the "actual average wholesale price" was only $3.69 – in other words, there *was a "spread" of over 170%.* (App. A, Tab 20.)

Fully aware that AWP does not reflect acquisition cost, the Government purposefully chose not to create a new reference point for reimbursement, and adopted compendia pricing –

[4] The Task Force was created under the auspices of the Department of Health, Education, and Welfare ("HEW," forerunner to the current Department of Health and Human Services "HHS").

and specifically, AWP – as the basis for reimbursement of various drugs under Medicare.[5] It also approved various state plans which adopted an AWP-based regime as their definition of EAC. The Government did not further define "AWP" either by statute or regulation – as the Government itself has confirmed. (*See, e.g.*, App. A, Tab 21 (HCFA, forerunner to CMS, states in 1998: "[w]e agree that the law does not define the term 'average wholesale price'")); *see also In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F.Supp.2d at 178 ("There are no regulations describing how AWPs are to be calculated, nor any regulatory process for approving them.").

As shown above, the Government knew AWP was a sticker price, but chose to use it as its reimbursement benchmark to effectuate various policy goals, including:

- **Administrative Convenience.** To promote efficiency and avoid administrative costs, the Government decided to use the already publicly available compendia. (*See, e.g.*, App. A, Tab 2 (In 1969 the HEW Task Force on Prescription Drugs acknowledged that the government based reimbursement on the compendia prices because it assumed "that any losses incurred by the program as a result of basing reimbursement on listed wholesale costs would be made up to the program in savings on auditing and other administrative costs . . . . This approach would have the advantage of administrative simplicity."); App. A, Tab 13 (HHS states, in 1991, that "[w]e believe that ultimately there should be a national fee schedule for [Medicare Part B] drugs. However, given the large number of different drugs and the myriad of dosage levels, we have decided that it is not practical for us to consider establishing a national drug fee schedule at this time.").)

- **Patient Access to Care.** The Government used the AWP-based reimbursement scheme to induce health care providers to participate in the Programs and ensure patients' access to medical care, which is the Programs' primary goal. *See* 42 U.S.C.

[5] In adopting the term "average wholesale price" into federal regulations and statutes, the Government is understood to have used the term as it was used by industry, rather than to have created a new term to be given its "plain meaning." *See, e.g.*, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 519 & n.16 (1992) (in interpreting a statute, a court looks to the statute's "regulatory context"; criticizing dissent for reading statute without looking at the "regulatory setting in which Congress acted"); *Corning Glass Works v. Brennan*, 417 U.S. 188, 201 (1974) ("[W]here Congress has used technical words or terms of art, it is proper to explain them by reference to the art or science to which they are appropriate.") (internal quotation marks and citations omitted); *see also Texas v. Sec'y of the Interior*, 580 F. Supp. 1197, 1213 (E.D. Tex. 1984) ("Words of art bring their art with them. They bear the meaning of their habitat whether it be a phrase of technical significance in the scientific or business work, or whether it be loaded with the recondite connotations of feudalism.") (citing Frankfurter, *Some Reflections on the Reading of Statutes*, 47 Colum. L. Rev. 527, 537 n.46 (1947)).

§ 1396a(30)(A) (1989) (Federal law requires States to set their Medicaid reimbursement rates at such a level to "assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area."); (App. A, Tab 23 (Letter from 89 Members of Congress to HHS Secretary Shalala notes that "oncologists are chronically underpaid for their drug administration services").)

- **Cross-Subsidization.** The Government realized that health care providers were not being fully reimbursed for their services under both Medicare and Medicaid. Thus, it intentionally implemented the AWP-based reimbursement system to ensure that health care providers were adequately reimbursed. (*See, e.g.*, App. A, Tab 14 (GAO reports, in 1993, that "HCFA and state Medicaid officials agreed that pharmacies must often use excess Medicaid reimbursements to cover their dispensing costs."); App. A, Tab 26 (OIG for HHS reports, in 2001, that HCFA recognized "that some providers now rely on inflated drug payments to cover other practice expenses."); App. A, Tab 30 (CMS reports, after a change in Medicare reimbursement in 2004, that "[w]e now have new tools to pay appropriately for each drug as well as the valuable services that go along with administering drugs, rather than having an overpayment for one subsidize an underpayment for the other.").)

In choosing AWP-based reimbursement, the Government expressly eschewed other approaches. (*E.g.*, App. A, Tab 9 (OIG for HHS recommends, in 1989, that Medicare "consider using a reimbursement method other than AWP . . . .") In fact, Congress has repeatedly forbidden federal agencies and states from changing the AWP-based methodologies – including changes proposed in 2000, 5 years after this suit was filed. (*See* App. A, Tab 12 (Congress, in 1990, imposed a 5-year moratorium on any reduction of Medicaid reimbursement for drugs); App. A, Tab 25 (Congress, in 2000, barred the Secretary of HHS from "directly or indirectly decreas[ing] the rates of reimbursement" for drugs covered by Medicare Part B until the Comptroller General studied the issue of Medicare drug reimbursement).)

In sum, the Government has known for decades that AWP and other compendia reported prices do not represent actual acquisition costs for pharmaceuticals. Indeed, it has known for years that AWP routinely exceeds acquisition costs by hundreds if not thousands of percentage points – it has even known of the specific allegations in *this case*, which was filed in 1995 but

just recently unsealed, for over a decade. Precisely because of this "spread," the Government made AWP the central feature of its Medicare reimbursement formulae, and permitted the States to use it as a basis for Medicaid reimbursement. It is these same AWPs that the current complaint now alleges were "fraudulent," specifically because they "were substantially higher than providers' actual acquisition costs" for the pharmaceutical products at issue here. (Compl. ¶ 103.)

ARGUMENT

I. EACH OF THE FOUR COUNTS MUST BE DISMISSED UNDER RULE 12(b)(6) FOR FAILURE TO STATE A CLAIM.

Dismissal of a complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) is appropriate "if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." *Blackston v. Alabama*, 30 F.3d 117, 120 (11th Cir. 1994) (citation omitted). While in ruling on this motion this Court must generally accept all well-pleaded facts as true, it "need not accept factual claims that are internally inconsistent, facts which run counter to facts of which the court can take judicial notice, conclusory allegations, unwarranted deductions, or mere legal conclusions asserted by a party." *Campos v. INS*, 32 F.Supp.2d 1337, 1343 (S.D. Fla. 1998); *see also Oxford Asset Mgmt., Ltd. v. Jaharis*, 297 F.3d 1182, 1188 (11th Cir. 2002) ("[C]onclusory allegations, unwarranted deductions of facts or legal conclusions masquerading as facts will not prevent dismissal."); *Browning v. Clinton*, 292 F.3d 235, 242 (D.C. Cir. 2002) ("Rule 12(b)(6) dismissal is appropriate where the allegations contradict the claim asserted. . . .") (citation omitted). In light of these standards, dismissal of each of Plaintiffs' four counts is appropriate.